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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 09/852,400 | 05/09/2001 | William L. Trepicchio | GFN-5405CP | 5404 |
| 5514 | 7590 | 03/12/2004 | EXAMINER | |
| FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | WHISENANT, ETHAN C | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1634 | | |

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/852,400 | TREPICCHIO ET AL. | |
| | Examiner | Art Unit | |
| | Ethan Whisenant, Ph.D. | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 DEC 03.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 43 and 44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 43 and 44 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

ELECTION/RESTRICTION

1. The applicant has elected without traverse Group II(a) : Claim 43-44, Drawn to a method of treating a subject afflicted with psoriasis or a TH1-associated condition which method comprises providing to cells of the subject afflicted with psoriasis or a TH1-associated condition a protein corresponding to a marker which marker is ID4. However upon reconsideration it is clear that an additional restriction requirement be made.

Upon reconsideration and after consultation with multiple Primary Examiners, an additional restriction requirement of Group II(a) needs to be imposed, see below.

2. Please note this is a group election not a species election.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group II(a) - 1 : Claim 43, Drawn to a method of treating a subject afflicted with psoriasis or a TH1-associated condition which method comprises providing to cells of the subject afflicted with psoriasis or a TH1-associated condition a protein corresponding to a marker which marker is ID4, classified in **Class 424, subclass 184.1**.

Group II(a) - 2 : Claim 44, Drawn to a method of treating a subject afflicted with psoriasis or a TH1-associated condition which method comprises providing to cells of the subject afflicted with psoriasis or a TH1-associated condition a protein corresponding to a marker which marker is ID4 and wherein the protein is provided is provided to the cells by providing a polynucleotide encoding the protein, classified in **Class 514, subclass 44**.

4. The inventions are distinct, each from the other for the following reasons.

Inventions II(a) - 1 and II(a) - 2 are drawn to two independent and distinct methods of treating a subject afflicted with psoriasis or a TH1-associated condition. In the first, a protein is administered to a subject in need thereof. In contrast, In the second invention a polynucleotide encoding said protein is administered to a subject in need thereof. These are two distinct inventions because polynucleotides and polypeptides are physically and functionally distinct chemical entities.

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The oligonucleotide of group II(a) - **2** and the protein of group II(a) - **1** are structurally and functionally distinct from each other. Proteins are composed of amino acid subunits while nucleic acids are composed of nucleotide subunits. Each group will require a non-coextensive literature search.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



ETHAN WHISENANT
PRIMARY EXAMINER

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